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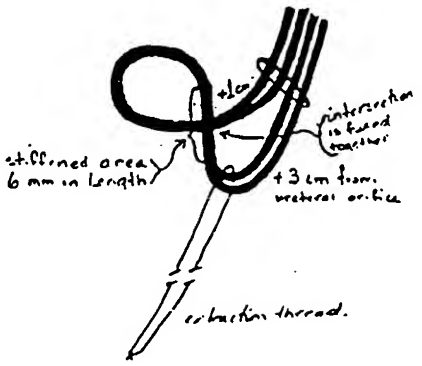
(54) Title: URETERAL STENT WITH SMALL BLADDER TAIL(S)

(57) Abstract

This invention is a ureteral stent (100) for assisting movement of urine along a patient's ureter and into the patient's bladder. The stent (100) includes an elongated tubular segment (130) extending toward the bladder from a kidney end region for placement in the renal cavity to a bladder end region. A central lumen (260) connects at least one opening (127) at the first end region to at least one opening in the bladder end region. At least one flexible tail (110) is attached to the bladder end region of the tubular segment (130) at a point outside the bladder so as to receive urine from the opening in the bladder end region of the tubular segment (130) and to transport urine from there across the ureter/bladder junction and into the bladder. The tail (110) includes an elongated external urine transport surface sized and configured to transport urine along the ureter. The urine transporting surface is sized and configured to extend along at least part of the ureter, across the ureter/bladder junction, and from there into the bladder.



Detail of threads

88 → ⊕

consequence of threads which are too cold (relatively) in compression

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URETERAL STENT WITH SMALL BLADDER TAIL(S)

Field of the Invention

This application relates to ureteral stents.

Background of the Invention

Ureteral stents are used to assist urinary drainage from the kidney to the bladder in patients with ureteral obstruction or injury, or to protect the integrity of the ureter in a variety of surgical manipulations. More specifically, stents may be used to treat or avoid ureter obstructions (such as ureteral stones or ureteral tumors) which disrupt the flow of urine from the kidneys to the bladder. Serious obstructions may cause urine to back up into the kidneys, threatening renal function. Ureteral stents may also be used after endoscopic inspection of the ureter.

Ureteral stents typically are tubular in shape, terminating in two opposing ends: a kidney (upper) end and a bladder (lower) end. The ends may be coiled in a pigtail or J-shape to prevent the upward or downward migration of the stent, e.g., with physiological movements. The kidney coil is designed to retain the stent within the renal pelvis of the kidney and to prevent stent migration down the ureter. The bladder coil sits in the bladder and is designed to prevent stent migration upwards toward the kidney. The bladder coil is also used to aid in retrieval and removal of the stent.

Ureteral stents, particularly the portion positioned in the ureter near the bladder and inside the bladder, may produce adverse effects including blood in the urine, a continual urge to urinate, strangury, and flank pain accompanying reflux of urine up the stent (e.g., when voiding) as pressure within the bladder is transmitted to the kidney. In short, stents may cause or

contribute to significant patient discomfort and serious medical problems. Figure 10 is a schematic drawing of the human urinary tract without a stent, showing the renal pelvis, the kidney, the ureter, and the ureteral orifices opening into the bladder. Figure 11 depicts a typical double-J stent 10 which comprises a small tube 12 which sits inside the urinary system and assists the flow of urine from the kidney (renal pelvis) to the bladder. Figure 12 depicts prior art indwelling ureteral stent 10 in position. Such stents are typically made of biocompatible plastic, coated plastic, or silicone material. Tube 12 typically varies in size from 4-8 fr. (mm in circumference), and it has multiple small holes throughout its length. A coiled shape pre-formed at each end 14 and 16 is designed to confine its movement within the urinary system, so that it will be maintained in the desired position. The upper (kidney) end 14 of the stent may be closed or tapered, depending on the method of insertion (e.g., the use of a guidewire). The tubular stent extends through the ureteral orifice 18a and into the bladder, fixing orifice 18a open, and thereby enhancing the opportunity for reflux. For clarity, the ureter entering bladder 20 through orifice 18b is not shown. A monofilament thread 22 may be attached to the bladder end of the stent for removal, usually without cystoendoscopy.

U.S. Patent No. 4,531,933 ("the '933 patent") discloses a ureteral stent having helical coils at each end which are provided for preventing migration and expulsion.

Summary of the Invention

We have discovered a ureteral stent design that avoids patient discomfort and urine reflux upward toward the kidney. Rather than rely on a tubular structure to contain and facilitate all (or, in some embodiments, any)

urine flow along the ureter, the invention features a thin flexible elongated tail member having an elongated external urine-transport surface. Urine flows along the outside surface of the structure, between that surface and the inside wall of the ureter. Without limiting ourselves to a specific mechanism, it appears that urine may remain attached to, and flow along, the external urine transport surface. The use of a foreign body that is as small as possible in the lower (bladder) end of the ureter and in the bladder itself decreases patient discomfort. Typically, the external urine transport surface is sized and configured to extend along at least part of the ureter near the bladder, across the ureter/bladder junction, and from there through the ureteral opening into the bladder.

While most or all of the length of the stent may rely on such an external surface to assist flow, more typically the stent will also include an upper elongated tubular segment to transport urine along a significant portion of the upper ureter. The upper tubular segment is connected at its lower end to an elongated tail which has the above described external urine-transport surface. The upper tubular segment comprises: a) an upper region having at least a first opening; b) a lower region having at least a second opening to be positioned in the ureter outside the bladder, and c) a central lumen connecting the first opening to the second opening. The elongated tail is a thin flexible tail member or filament(s) extending from the lower region of the tubular segment at a point outside the bladder so as to receive urine from the second opening of the tubular segment and to transport urine along the ureter from the lower region of the tubular segment across the ureter/bladder junction and into the bladder. Typically, but not exclusively,

the upper region of the tubular segment is configured and sized for placement in the renal cavity.

Typically the elongated tail member comprises at least one (and more preferably at least two) thread filament(s). Two or more of the filaments may be configured in at least one filament loop, and, advantageously, the tail comprises no unlooped filaments, so that the tail is free from loose ends. The loop(s) can be made by joining the ends of a single filament, in which case the filament loop comprises a junction of individual filament ends, which junction typically is positioned at the point where tail joins to the elongated tubular segment. Preferably, the tail is long enough to effectively prevent migration of the entire tail into the ureter, and the tail has a smaller outer diameter than the outer diameter of the tubular segment.

The tubular stent segment is stiff enough to avoid crimping during insertion through the ureter, so that it can be inserted by typical procedures. The tail, on the other hand, is extremely flexible (soft) in comparison to the tubular segment, and it has a much smaller diameter than the tubular segment to avoid discomfort. Even quite thin structures will provide urine transport, and the thinner and more flexible the tail is, the less likely it is to cause patient discomfort. On the other hand, the tail (and its connection to the rest of the stent) should have sufficient strength so the stent can be retrieved by locating the tail in the bladder and pulling on the tail to retrieve the stent from the kidney and ureter. Details of the tail size are discussed below. The use of reinforcing materials (e.g., sutures as described below) permits the use of thinner tails while still providing the ability to locate the tail in the bladder and to retrieve the stent. The tail may be a suture, and the suture may be coated to avoid encrusting.

The external urine-transport surface of the tail can be convex (circular or oval in section), concave or flat. The tail filament may be fluted. The tail may, but need not, include an accurately shaped anchor segment to control migration up the ureter. The tail may be either solid or hollow; even when hollow, it is not designed to transport a significant amount of urine internally. The tail may also be tapered.

The upper region of the tubular segment may have a portion designed for placement in the renal cavity, which portion has enlarged diameter and/or straight sides and corners. The stent may include an extractor thread attached to the lower end of the elongated tail member.

To make the stent, the tail may be molded in one piece with the tubular segment, or it may be made separately and attached to the bladder end region of the tubular segment at a point toward the kidney from the bladder end of the lower region of the tubular segment. In one specific embodiment, the tail is attached near or at the bladder end of the bladder end region of the tubular segment. The stent may include a suture securing the tail to the tubular segment, and the suture may be incorporated into the tail to impart strength to the tail so the tail may be used to retrieve the stent. If the tail includes a hollow lumen, the suture may be positioned inside that lumen. The suture may be attached to the tubular segment at a point in the bladder end region of the tubular segment, and the suture may extend from the point of attachment through an opening in the bladder end region to the central lumen of the tubular segment and from there to the hollow tail. Alternatively, at least the bladder end region of the tubular segment may include two lumens, a main urine-transporting lumen and a bladder lumen to encase the suture, so that the suture does not become encrusted.

The outer diameter of the tubular segment can be tapered so that it decreases approaching its lower region. The lower region of the tubular segment may include multiple openings positioned, e.g., axially along include its length or radially around its circumference, or in other patterns. In addition, the outer diameter of the stent's tubular segment may decrease approaching the upper region. In other words, the maximum diameter may be at the site of the injury to encourage a sufficiently large inner diameter in the repaired structure, and the tubular segment's outer diameter may decrease moving away from that point of maximum diameter to sections of the normal ureter that are not in need of a broad support structure. Typically, the outer diameter of the upper end of the tubular segment will be greater than the outer diameter of the bladder end. The upper region may include multiple openings (inlets).

In an alternative embodiment, the elongated external urine-transport surface is a continuous surface extending from the kidney to the bladder, e.g., it is the outer surface of a solid member extending from the kidney to the bladder.

Another aspect of the invention features a method of introducing a ureteral stent (described above) into a patient, by (a) positioning the kidney end region of the tubular segment within the renal pelvis; and (b) positioning the elongated flexible member(s) in the bladder.

Yet another aspect of the invention features a method of manufacturing a ureteral stent as described above. The method comprises: (a) providing a polymer pre-form having a tubular shape; (b) forming an elongated tubular stent segment from the polymer pre-form, and (c) providing tail member(s) at an end region of the tubular

segment designed to be positioned toward the patient's bladder.

As described in greater detail below, the stent may be manufactured from a polymer form having a tubular shape by forcing the form onto a mandrel to produce the desired three dimensional shape (coils, etc.). The elongated tubular member(s) is attached to one end of the tubular member(s) using sutures as described above. Heat treatments to fuse the structures and/or standard adhesives may be used. Alternatively, the tubular member(s) and the elongated member constitute a one-piece stent.

The use of relatively thin, flexible elongated member(s) to assist urine flow across the ureterovesical junction and into the bladder may reduce reflux and irritation and thereby reduce patient discomfort and medical problems associated with ureteral stents.

Other features and advantages of the invention will appear from the following description of the preferred embodiment, and from the claims.

Brief Description of the Drawings

Figure 1 is a side view of a ureteral stent with a central portion of the tubular segment omitted.

Figure 2 is a cross-sectional view along line 2-2 in Figure 1.

Figure 3 is an enlarged side-view of a portion of the ureteral stent in Figure 1.

Figure 4A is a view of an alternate embodiment of the stent in Figure 1, and Figure 4B is a section taken along 4B-4B of Figure 4A.

Figures 5A and 5B are schematic representations of another stent according to the invention, depicted in place.

Figures 6A-6D depict alternative cross-sections of the tail of a stent according to Figure 5.

Figure 7 is a schematic representation of yet another stent according to the invention, having an extraction thread.

Figure 7A is an enlargement of a portion of Figure 7.

Figure 8-8 is a schematic representation of the stent of Figure 7 shown in position.

Figure 8A is a detail of the connection between the tail and the extraction thread.

Figure 8B is a cross-section of threads of differing softness, showing the effect of compression on interstitial space.

Figure 9 shows an alternative embodiment of the stent.

Figure 10 is a schematic drawing of the human urinary tract without a stent, showing the renal pelvis, the kidney, the ureter, and the ureteral orifices opening into the bladder.

Figure 11 depicts a prior art double-J stent outside the body.

Figure 12 depicts a prior art J indwelling ureteral stent in position.

Description of the Preferred Embodiments

In Figure 1, ureteral stent 100 includes an elongated tubular body 130 connecting coil end 140 to straight end region 120. Tubular body 130 is designed to extend from the renal pelvis through the ureter to a terminus upstream of the bladder. Tail 110 is attached to straight end region 120, and tail 110 extends along the ureter, across the ureter/bladder junction and into the bladder.

The two opposing end regions 120 and 140 of elongated tubular body 130 are illustrated in Figure 1. Coiled end region 140 is designed to be placed in the renal pelvis of the kidney. For illustrative purposes,

coiled end region 140 is shown with a pigtail helical coil although any shape that will retain the stent in place within the kidney will do. Coiled end region 140 includes several openings 125 placed along the wall of the tubular body; the openings may be arranged in various geometries (e.g., axial, circumferential, spiral). The entire tubular segment, including the region between the kidney and the bladder end regions, may include additional openings.

The bladder end region 120 of the tubular stent segment is designed to terminate in the ureter, upstream of the bladder. For purposes of further description, the end region of stent 100 received in the kidney will be designated the kidney end and the opposite end of stent 100 toward the bladder will be termed the bladder end.

Figure 2 is a cross-sectional view of stent 100 of Fig. 1. In Fig. 2, elongated tubular body 130 has annular walls 250 having an inner and outer diameter. The outer diameter of tubular body 130 may be substantially uniform throughout much of the length of the tube, or it may taper from a relatively short region of larger diameter (the site of the repair, where there is a risk that the healing process will substantially restrict flow in the lumen) to a region of generally small diameter. The precise configuration may depend on the ureteral defect being corrected. Just one of the many classes of procedures that can benefit from the stent are endopyelotomies -- procedures for treating ureteropelvic junction (UPJ) obstruction by an incision which perforates the ureter at the stricture. In these and other procedures, the stent keeps the ureter lumen open during the healing process; so that the inner diameter of the resulting healed structure is adequate. The section of the tubular segment at the defect is large enough to support growth of repair tissue having an

adequate inner diameter. At other sections of the ureter (e.g., sections not being surgically repaired), the outer diameter of the tubular segment may be far smaller, but with an inner diameter adequate for passage over a guidewire. For example, the outer diameter of the bladder end region of the tubular segment typically is 2Fr.-12Fr. Preferably the outer diameter of tubular body 130 is greatest at the ureteropelvic junction obstruction but begins to taper approaching each end. Alternatively, for a patient with an upper ureteral obstruction, the upper (kidney) portion of the tubular member 130 may be uniform in diameter, tapering just in the lower (bladder) portion.

Tubular member 130 defines a central lumen or passageway 260, extending from kidney end region 140 to bladder end region 120. The inner diameter of lumen 260 is sufficient to permit passage over a guidewire. Tubular body 130 may also have openings 125 extending through its walls 250 to facilitate the flow of urine from the kidney into central lumen 260 and openings 127 to facilitate flow out of central lumen 260.

In Fig. 3, the outer diameter of elongated tubular body 130 tapers near bladder end region 120. The outer diameter of bladder end region 120 may be made as small as possible while maintaining the ability to pass over a guidewire. Elongated tubular body 130 may (but need not be) substantially straight in bladder end region 120, i.e. it does not coil or curve in the absence of external force. When tail 110 is a single filament, it typically is thinner than even the smallest portion of bladder end region 120 of the tubular stent segment. Alternatively, it may be desirable to design the tail from multiple filaments, each of which, by itself, is much thinner than the bladder end region of the tubular stent segment. Together, such a multi-filament tail has a larger

effective diameter, providing additional bulk while maintaining comfort. Tail 110 may be attached at or near the end of region 120, and it extends from that attachment into the bladder. Tail 110 is either solid or hollow. It can be generally cylindrical in shape; alternatively, it can be fluted, concave (quarter-moon)-shaped or it may assume other shapes.

The tail can have an outer diameter that is significantly less than the inner diameter of the ureter (typically 2-5mm) and no greater than the outer diameter of the tubular segment from which it extends. For example the tail diameter is less than 10Fr. and as low as a suture (about 0.5Fr). Preferably the tail diameter is between 2Fr. and 4Fr. The length of tail 110 is preferably between 1 and 100cm. In one embodiment, the tail is long enough so that at least a portion of it will remain in the bladder, and effectively the entire tail cannot migrate up into the ureter. Preferably the length is between 1 and 40cm. Tail 110 is flexible and, upon application of force, can be curved, but also has memory such that when the force is removed, it is generally straight.

Stent 100, including tail 110 and tube 130, may be a single unit. Thus, tail 110 can be a unified piece, extending from bladder end region 120 with no additional attachment means. Alternatively tail 110 can be secured to elongated tube 130 or bladder end region 120 by physical or mechanical methods.

For example, in Fig. 4A, a suture 415 is inserted through an opening 418 in the tubular member and then threaded through the lumen 417 of tubular member 430. In Fig. 4B, tail 410 is a hollow member having suture 415 threaded through its inner lumen 412.

Fig. 5 is a schematic of another stent 510. The kidney end A of the stent has a pre-formed memory bend,

to coil 512 as shown. Kidney end A is larger and more rectangular to help prevent upward as well as downward stent migration. End A may be closed or tapered to accommodate various insertion techniques. For the upper portion (A--B) of the stent, diameter, lumen size, perforations and materials are conventional. The lower end 514 of the tubular stent segment ends at B. The distance A--B could vary depending on the patient's anatomy. At B, the stent is tapered (or at least smooth and constant in diameter).

Two or more monofilament or coated (plastic or silicone) threads 516 exit from the lumen or from the stent wall. These threads only partially fill the ureter and are as flexible (soft) as possible. Typically, they are cut to a length which forces confinement within the bladder.

The portion of the upper segment 512 lying within the renal pelvis (e.g, from the kidney end of the stent to point A) is expanded so that it is larger in section, and it may even be oval or rectangular in cross-section, to help prevent upward as well as downward stent migration. The kidney end of the stent may be closed and/or tapered to accommodate the desired insertion technique. The upper portion 512 is made of a relatively stiff material (among the materials currently used in ureteral stents), and it should be designed to effectively restrict the motion of the stent to prevent proximal as well as distal migration of the catheter during normal physiological activity (required because the lower pre-formed portion is deleted). The length of the straight portion of the upper segment (Fig. 5A point A to B) will vary with patient size and anatomy. In the preferred configuration, the upper segment extends more than halfway down the ureter when in proper position. The lowest end of the upper segment (Fig. 5A point B)

should be tapered or beveled to facilitate withdrawal. Otherwise, the upper segment is a typical stent in diameter, materials and shape.

The lower segment (Fig. 5A point B to point C) consists of two or more (e.g four) monofilament, plastic coated or silicone coated threads (shown in section in Fig. 5B) which extend from the lumen or sidewall of the lower end of the upper segment (Fig. 5A point B) along ureter 513 into the bladder. These threads are extremely flexible, and their diameter is selected to maintain a passage for urine flow and yet drastically reduce bladder and ureteral irritation. By avoiding distortion of the ureter wall, the threads may inhibit urinary reflux as well. The threads should be long enough to reach well into the bladder (Fig. 5A point C), but not so long as to wash into the urethra with voiding. One thread 518 (or two or more threads in a loop) may be long enough to exit through the urethra (Fig. 5A point B to point D) to permit ready removal by pulling (avoiding cystoendoscopy).

These extended threads may also be used for stent exchange, in which a second catheter is exchanged for the catheter already in place. According to that procedure, these extended threads are captured with a snare that has been inserted through the central lumen of a second catheter. The snare is used to pull the threads through the lumen as the second catheter is advanced into the ureter. A guidewire is then inserted through the central lumen of the second catheter to the kidney (outside the first catheter's tubular body). The first stent is then removed by pulling on the threads, leaving the guidewire in position for placement of a new stent using standard techniques.

Figs. 6A-6D are alternative cross sectional sketches (taken at the same location as Fig. 5B) of some

possible arrays of threads passing within the lower ureter 517. Multiple threads 516 (2 and 4, respectively) are shown in Figs. 6A and 6B. A substantially similar conduit could be achieved by fluted type cross sections in a single filament Figs. 6C and 6D). The shapes of Figs. 6C and 6D could also be effective in reducing stiffness and hence irritability at the bladder end (i.e., lower segment), e.g., in a single filament design. Multiple threads may have the advantage of better surgical manipulability and superior comfort to the patient.

Further refinements are described below and in Figs. 7 and 7A which deal with: a) proximal or upward stent migration of either the entire stent or individual threads in the lower segment independent of upper segment movement; b) bunching of one or more threads within the ureter so as to obstruct flow or cause ureteral injury or knotting at the time of removal; and c) in multi-thread embodiments, discomfort and/or reduced drainage through the ureter resulting from the use of threads of different lengths. In Fig. 7, 6 F (F = French size = circumference in mm) stent is a generally a good size for adult urinary systems. It is large enough to provide good drainage and small enough to minimize local irritation and inflammation of the ureter. In this embodiment, the upper segment need be only a single loop of conventional size because a change in the design of the lower segment (see later discussion and Fig. 8) should prevent proximal migration. The upper segment (Fig. 7 point A to point C) is constructed of a relatively firm material because, during insertion, the pusher tubing should be removed after the guidewire is removed. This means that there will be some drag on the threads during removal of the pusher tubing which could dislodge the stent if the coil (Fig. 7 point A to point B, about 2.5 cm) does not

provide adequate resistance. The coil may be tapered or closed depending on the insertion technique desired (i.e., over a previously placed guidewire.

Fig. 7 point B to point C should have an approximate length of 12 cm. This is long enough to prevent dislocation of the upper segment in a large renal pelvis and short enough to end well above the point where the ureter crosses the common iliac vessels. At the iliac vessels, the ureter takes a fairly sharp turn and the threads will more easily follow the natural curves at this point. This design should reduce the inflammation that is normally seen in this region when a conventional double-J stent is left indwelling on a chronic basis.

The junction of the upper and lower segments at Fig. 7 point C is important. See Fig. 7A, which enlarges this junction. At point C (Fig. 7) the threads are attached to the upper segment in a manner that achieves the following goals: 1) the threads are securely attached to the upper segment and to each other (at least for a short distance of about 0.8 mm) so that their orientation to themselves is maintained (to the maintenance of lower end asymmetry); 2) the threads do not obstruct the lumen of the upper segment and they allow for the easy passage of a standard guidewire (e.g., 0.035 guidewire); 3) the transition diameters in this region closely preserve the 6F standard so that this point can pass in both directions smoothly throughout the instruments used for insertion and through the ureter; 4) there is no cause for a localized ureteral obstruction; and 5) there is an effective abutment for the pusher tubing. For an average size ureter a good starting string diameter for a four string lower segment (Fig. 7 point C to point E) would be 0.020 inches. A simple monofilament nylon thread is an easy potential solution but may be too stiff. A more supple monofilament or woven thread with silicone or

other coating may be required to achieve minimal irritability. However, the threads should be sufficiently resistant to compression so that tissue generated pressures cannot collapse the interspaces of the threads. See Fig. 8B, showing cross-sections of threads (left) which retain interstitial space under some modest compression and of threads (right) which are so soft that they compress into a plug with reduced interstitial space. These threads may have centimeter markings beginning at a point no more than 20 centimeters from point B (Fig. 7) so that functional ureteral and total stent length may be noted.

The portion of the lower segment which lies within the bladder when the stent is in proper anatomic position (Fig. 7 point D to point E) is important to both comfort and function. Proximal migration can be controlled by using asymmetrical lengths of the thread pairs, with one pair being 2 cm longer that the other pair, so that the fused junction of these threads tends to intersect with the ureteral orifice at and angle (e.g., ~90°) with the stiffened length of 6 mm (see detail Fig. 8B). In the ideally fitted stent of this embodiment, the thread pairs will extend beyond the ureteral orifice (Fig. 7 point D) by 1 cm at the short limb and 3 cm at the long limb. However, this lower segment configuration allows for considerable tolerance in sizing (unlike unsecured independent threads which must be selected to have a length so as to avoid upward migration of the thread through the ureter orifice) and a chosen length which is 1 cm shorter or 2-3 cm longer than the ideal length should be satisfactory. Using this configuration the threads should form a continuous loop of 3.5 cm length to prevent free ends from poking the bladder wall or prolapsing through the urethra. Buoyant threads may add to patient comfort, because they will float away from the

trigone region of the bladder, where most of the sensory nerve fibers are located. A typical small gauge filament extraction thread may be attached to the longer limb of the thread pairs, which is a suitable pulling point for removal.

From this embodiment, a small diameter pusher tubing of 4--4.5 F should be used to aid insertion. Soft percuflex is near optimal for the lower segment, and firm or regular percuflex is used for the upper segment.

The bladder end should be easily inserted using instruments, and it should prevent proximal migration of the stent. The design of Fig. 7 will avoid tangling and migration of the stent. Alternatively, soft percuflex, for example, has good resistance to extreme flexion at small radii (e.g., even 0.020" diameter) so that a simple continuous loop extending from the junction of the upper and lower segments (see Fig. 9) may be adequate to prevent upward migration. The design of Fig. 9 also has the advantage of relative ease of manufacture and relative ease of insertion, as well as ease and comfort of removal.

Other dimensions that can be used (without limitation) are 12 cm straight portion of the upper hollow shaft, and 12 cm, 14 cm, or 16 cm length of added loops of soft percuflex. For the 0.020" diameter material, either 2 or 3 loops may be used providing 4 or 6 strings, total. For 0.040" inch material, either 1 or 2 loops is recommended.

Fig. 9 shows such an alternative embodiment having a simple coil at the kidney end. The lower end is constructed of looped stringlike elements with ends fused at the junction between the lower and the upper end. Therefore, there are an even number of string elements, with no free ends. Circle E in Fig. 9 represents an idealized depiction of the ureteral opening into the

bladder. While not shown in Fig. 9, the loops may be fused over a very short distance at the bladder end in order to prevent tangling of loops and to improve stent handling. Any conventional means of fusion may be used. Optionally, organization of the loops can be maintained by pre-placing them inside the pusher tubing using a long monofilament nylon loop tail, similar to those used for the non-invasive removal stents (i.e. without sensor endoscopy).

Methods for insertion and removal of ureteral stents are known in the art. Generally, stent placement is achieved by advancing the tubular stent segment over a guidewire in the ureter. A pushing catheter passes the tubular segment into the kidney, while maintaining the tail in the bladder. Other methods such as a stiff sheath can be used to position the stent. Once in position, the sheath can be removed.

The tubular portion of the stent may be manufactured by extruding a tube according to known techniques. The elongated tail may be separately manufactured by conventional techniques and attached to the tubular portion, e.g., using biocompatible adhesive materials or heat. Alternatively, the stent may be made by injection molding the tube and the tail as a single piece, using a pin to create hollow segments. The stent may be manufactured from any of a number of biocompatible polymers commonly used inside the body, including polyurethane and polyethylene. In still other embodiments, the entire stent may be solid, so that urine is conveyed entirely on an external stent surface.

What is claimed is:

1. A ureteral stent for assisting flow of urine within a patient's ureter and into the patient's bladder, the stent comprising a thin flexible elongated member having an elongated external urine-transport surface sized and configured to transport urine along the surface within the ureter.

2. The stent of claim 1 in which the external urine transporting surface is sized and configured to extend along at least part of the ureter, across the ureter/bladder junction, and from there through the ureteral opening into the bladder.

3. The stent of claim 2 further comprising an elongated tubular segment attached to said elongated member, the tubular segment comprising:

a) an upper region having at least a first opening,

b) a lower region having at least a second opening to be positioned in the ureter outside the bladder, and

c) a central lumen connecting the first opening to the second opening;

the elongated member being at least one thin flexible tail extending from the lower region of the tubular segment at a point outside the bladder so as to receive urine from the second opening of the tubular segment and to transport urine from the second region across the ureter/bladder junction and into the bladder.

4. The stent of claim 3 in which the upper region is configured and sized for placement in the renal cavity.

5. The stent of claim 1 or claim 3 in which the elongated member is a tail comprising at least one thread filament.

6. The stent of claim 5 in which the tail comprises multiple thread filaments.

7. The stent of claim 5 in which the tail comprises at least one filament loop.

8. The stent of claim 7 in which the tail comprises no unlooped filaments, so that the tail is free from loose ends.

9. The stent of claim 7 in which the filament loop comprises a junction of individual filament ends.

10. The stent of claim 9 in which the junction of filament ends is positioned at the point where tail joins to the elongated tubular segment.

11. The stent of claim 6, comprising at least two filaments loops.

12. The stent of claim 3 in which the elongated member is softer than the elongated tubular segment.

13. The stent of claim 4 in which the upper region comprises a portion of enlarged diameter, designed for placement in the renal cavity.

14. The stent of claim 13 in which the upper region has an external section having straight sides and corners.

15. The stent of claim 5 in which the tail is a fluted filament.

16. The stent of claim 1 further comprising an extractor thread attached to the lower end of the elongated member.

17. The stent of claim 3 in which the external urine-transport surface is concave.

18. The stent of claim 3 in which the external urine-transport surface is convex.

19. The stent of claim 3 in which the tubular segment is stiff enough to avoid crimping during insertion through the ureter.

20. The stent of claim 3 in which the tail and its attachment to the tubular segment are strong enough to permit retrieval of the stent from the kidney and ureter by locating the tail in the bladder and pulling on it.

21. The stent of claim 3 in which the tail includes an accurately shaped anchor segment to control migration up the ureter.

22. The stent of claim 3 in which the tail is long enough to effectively prevent migration of the entire tail into the ureter.

23. The stent of claim 3 in which the tail has a smaller outer diameter than the outer diameter of the tubular segment.

24. The stent of claim 3 in which tail is solid.

25. The stent of claim 3 in which at least part of the tail is hollow.

26. The stent of claim 3 in which the outer diameter of the tubular segment decreases approaching the bladder end region.

27. The stent of claim 3 or claim 26 in which the tubular member includes multiple openings along its length.

28. The stent of claim 3 in which the outer diameter of the tubular segment decreases approaching the kidney end region.

29. The stent of claim 3 in which the kidney end region includes multiple openings.

30. The stent of claim 3 in which the tail is attached to the bladder end region at a point toward the kidney with respect to the bladder end terminus of the bladder end region.

31. The stent of claim 26 further comprising a suture securing the tail to the tubular segment.

32. The stent of claim 31 in which the suture is incorporated in the tail to impart strength to the tail.

33. The stent of claim 32 in which the tail comprises a hollow lumen and the suture is positioned inside the hollow tail lumen.

34. The stent of claim 33 in which the tail is hollow, and the suture is attached to the tubular segment at a point toward the kidney with respect to the bladder end terminus of the bladder end region of the tubular segment, and the suture extends toward the bladder from the point of attachment through an opening in the bladder end region to the central lumen of the tubular segment and from there along the inside of the tail.

35. The stent of claim 3 in which at least the bladder end region of the tubular segment comprises multiple lumens, one of the lumens enclosing the suture from the point of attachment to the tubular segment to the terminus of the bladder end region.

36. The stent of claim 1 wherein the elongated external urine-transport surface is a continuous surface extending from the kidney to the bladder.

37. The stent of claim 36 wherein the elongated external surface is the outer surface of a solid member extending from the kidney to the bladder.

38. The stent of claim 3 wherein the tubular member and the elongated member comprise a one-piece stent.

39. A method of introducing a ureteral stent into a patient, the stent comprising a) a thin flexible elongated member having an elongated external urine-transport surface sized and configured to transport urine along the surface within the ureter; and b) an elongated tubular segment attached to said elongated member, the tubular segment comprising: i) an upper region having at least a first opening, ii) a lower

region having at least a second opening to be positioned in the ureter outside the bladder, and iii) a central lumen connecting the first opening to the second opening; the elongated member being a thin flexible tail extending from the lower region of the tubular segment at a point outside the bladder so as to receive urine from the second opening of the tubular segment and to transport urine from the second region across the ureter/bladder junction and into the bladder, the method comprising:

(a) positioning the kidney end region of the tubular segment within the renal pelvis; and

(b) positioning the elongated flexible member in the bladder.

40. A method of manufacturing a ureteral stent, the stent comprising a thin flexible elongated tail member having an elongated external urine-transport surface sized and configured to transport urine along the surface within the ureter, the method comprising:

providing a polymer pre-form having a tubular shape, forming an elongated tubular stent segment from the polymer pre-form, and

providing a tail member at an end region of the tubular segment designed to be positioned toward the patient's bladder.

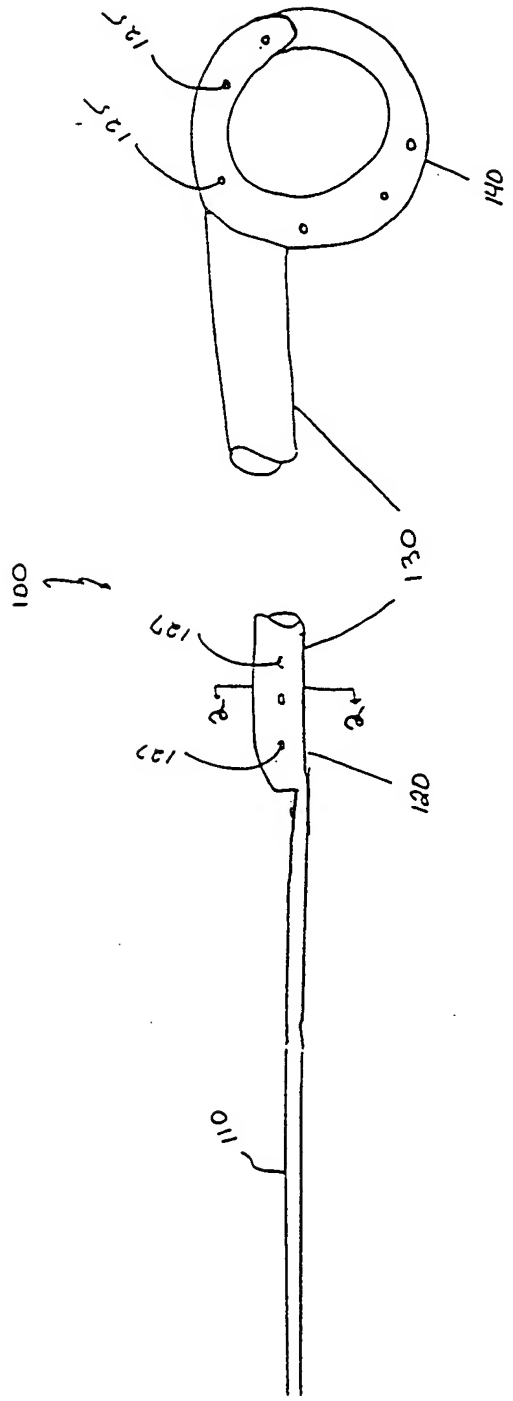


FIGURE 1

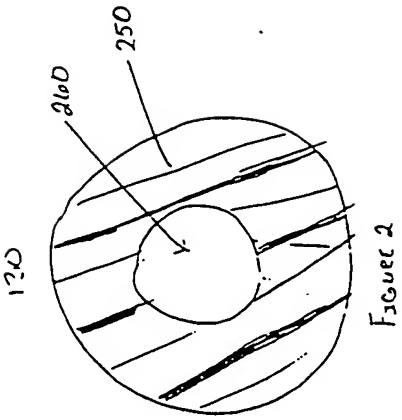


FIGURE 2

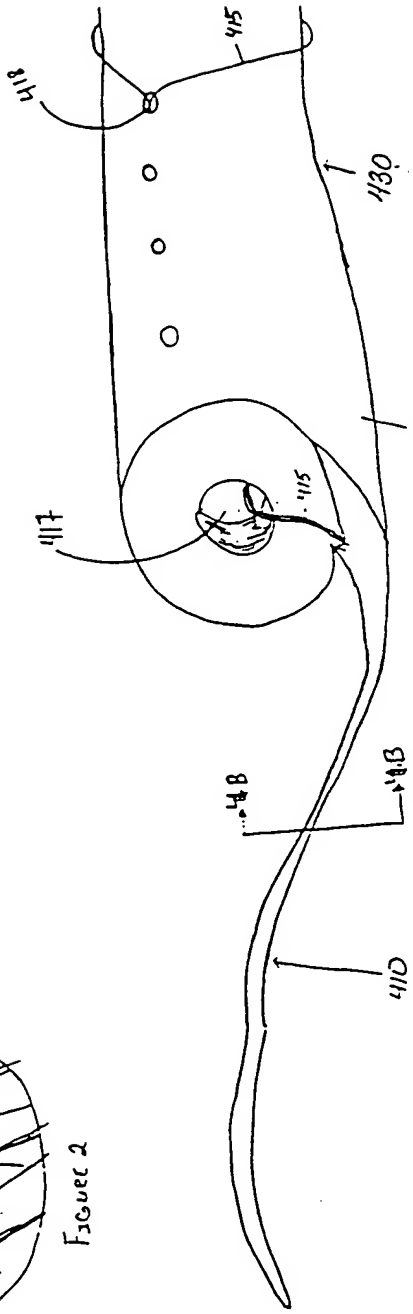


FIGURE 4A

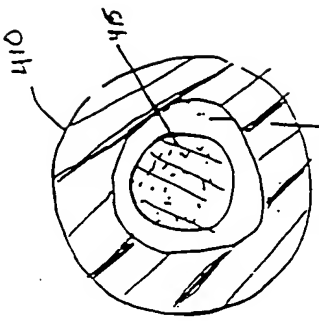


FIGURE 4B

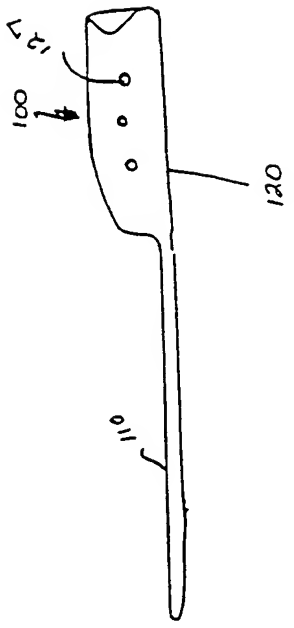


Figure 3

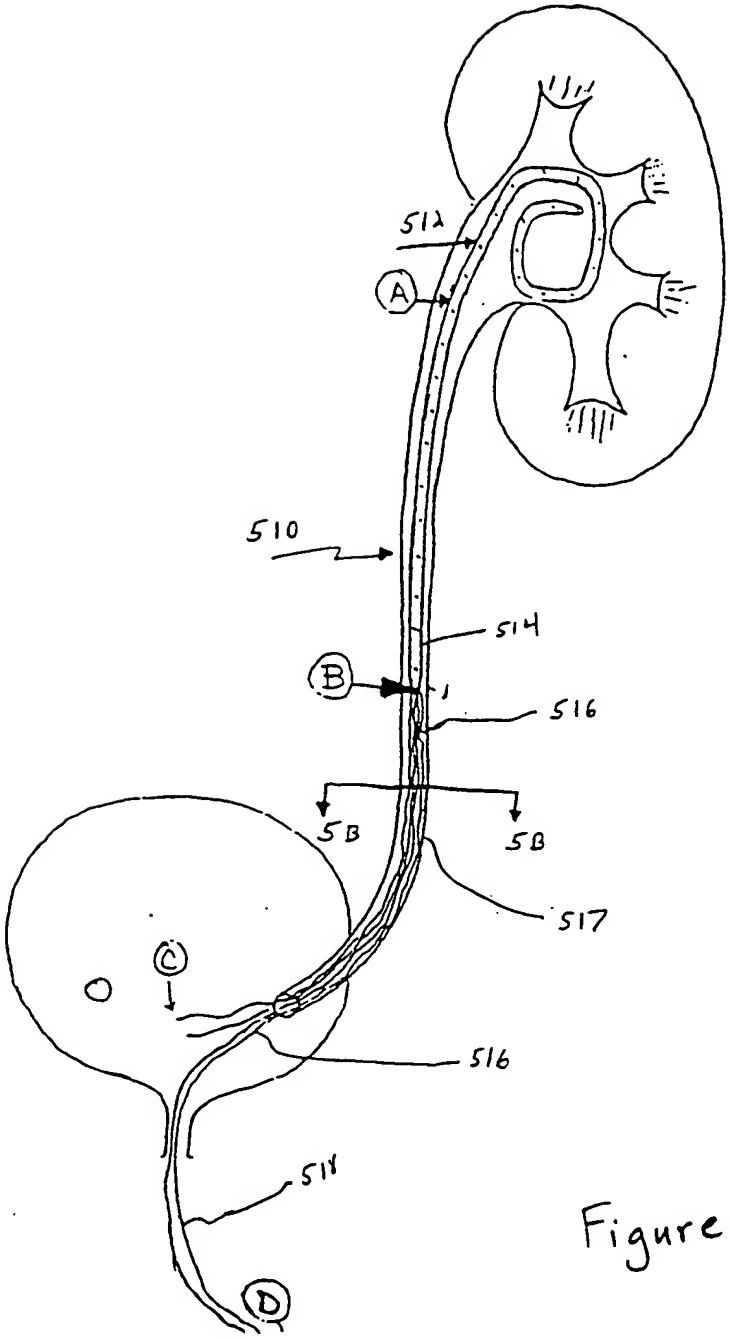


Figure 5A

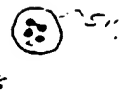


Figure 5B

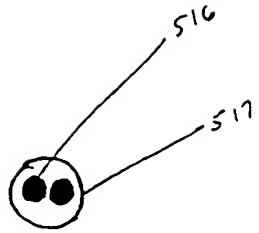


Figure 6A

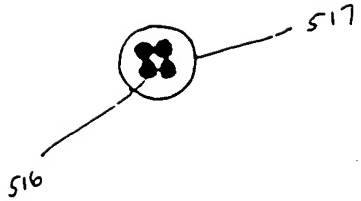


Figure 6B

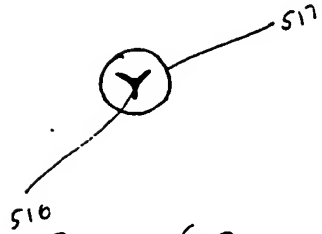


Figure 6C

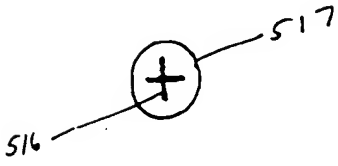


Figure 6D

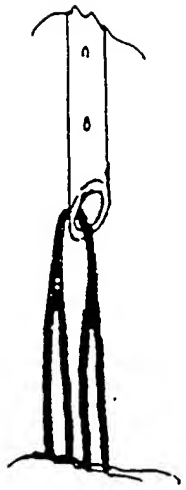


Figure 7A

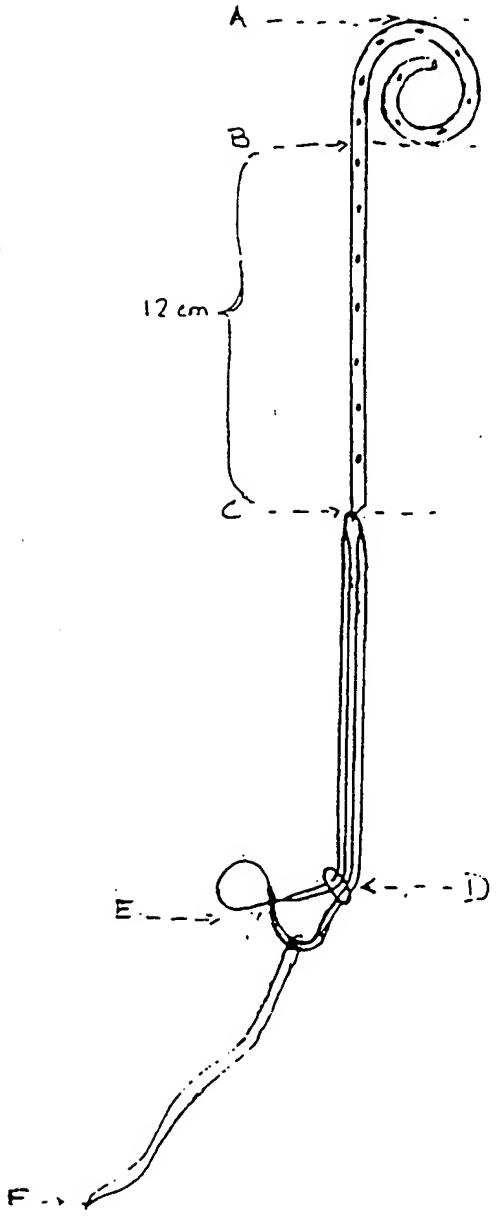


Figure 7

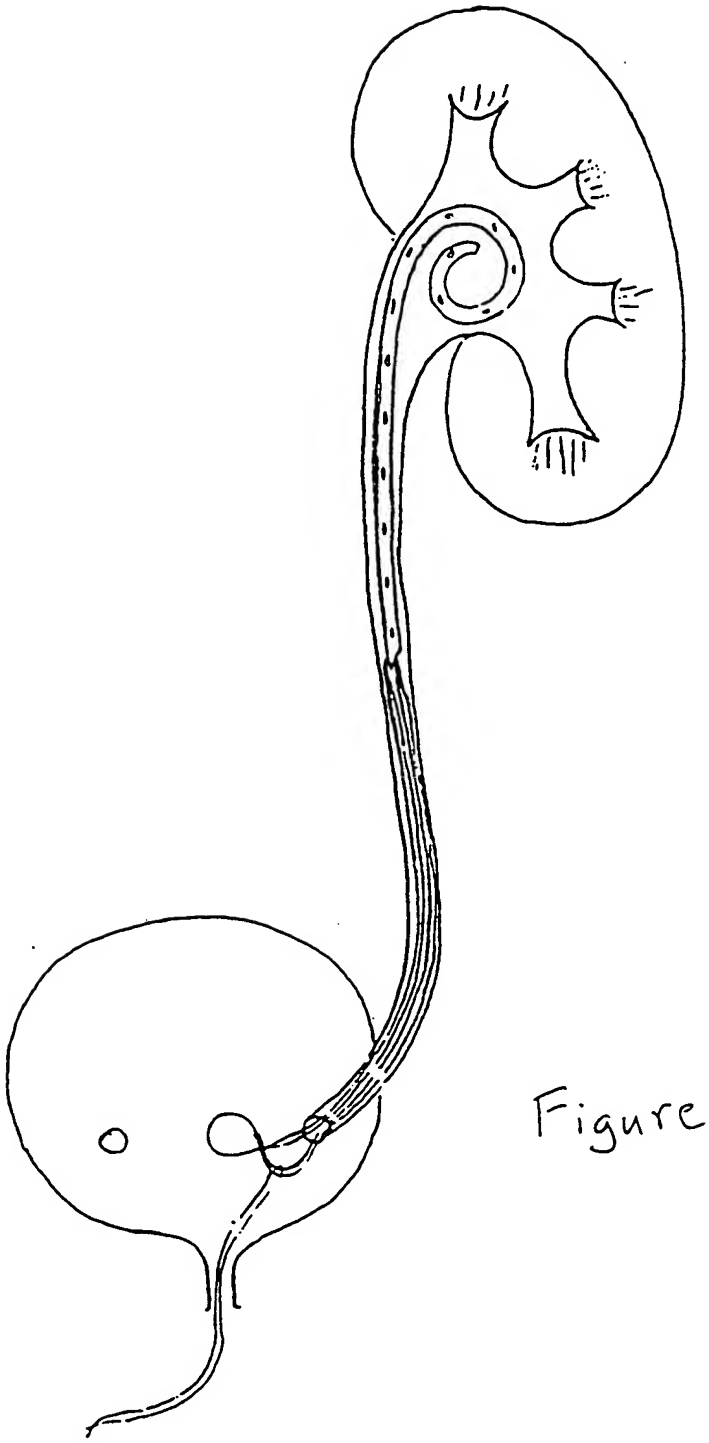


Figure 8

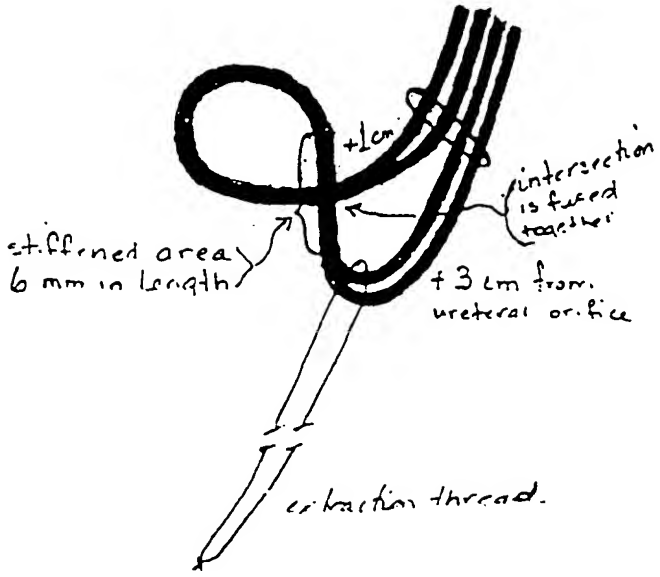


Figure 8A

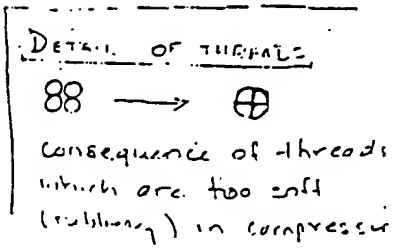


Figure 8B

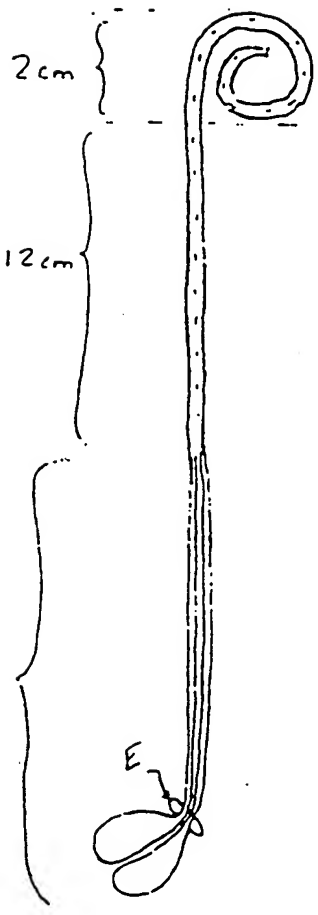
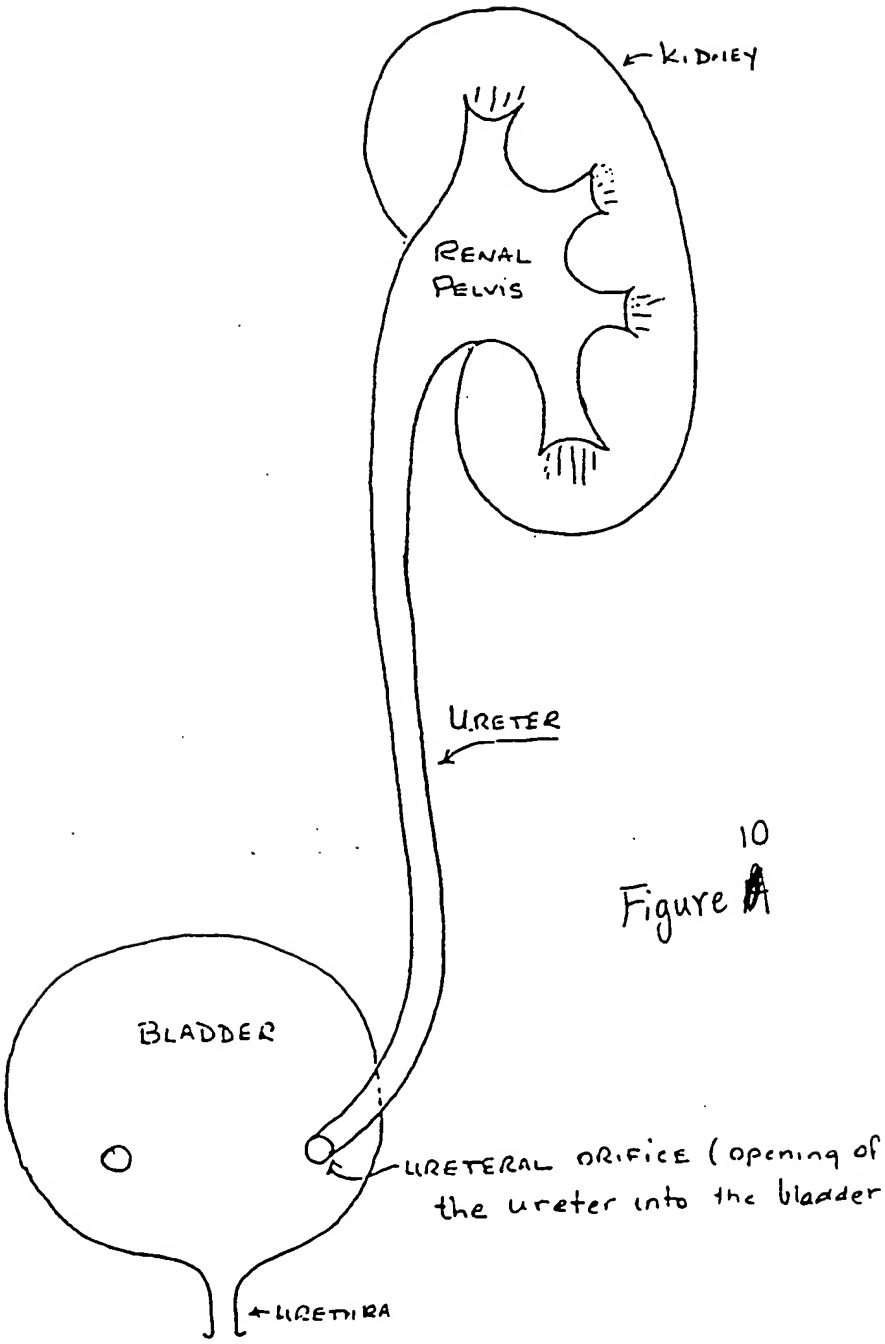


Figure 9


KIDNEY
RENAL PELVIS
URETER
BLADDER
URETERAL ORIFICE (opening of the ureter into the bladder
URETHRA

10

Figure 1

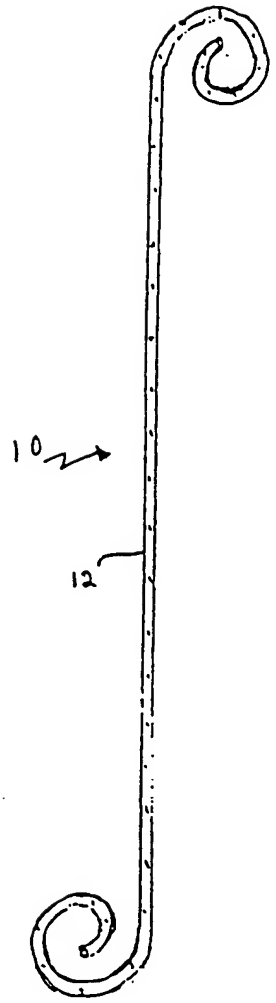
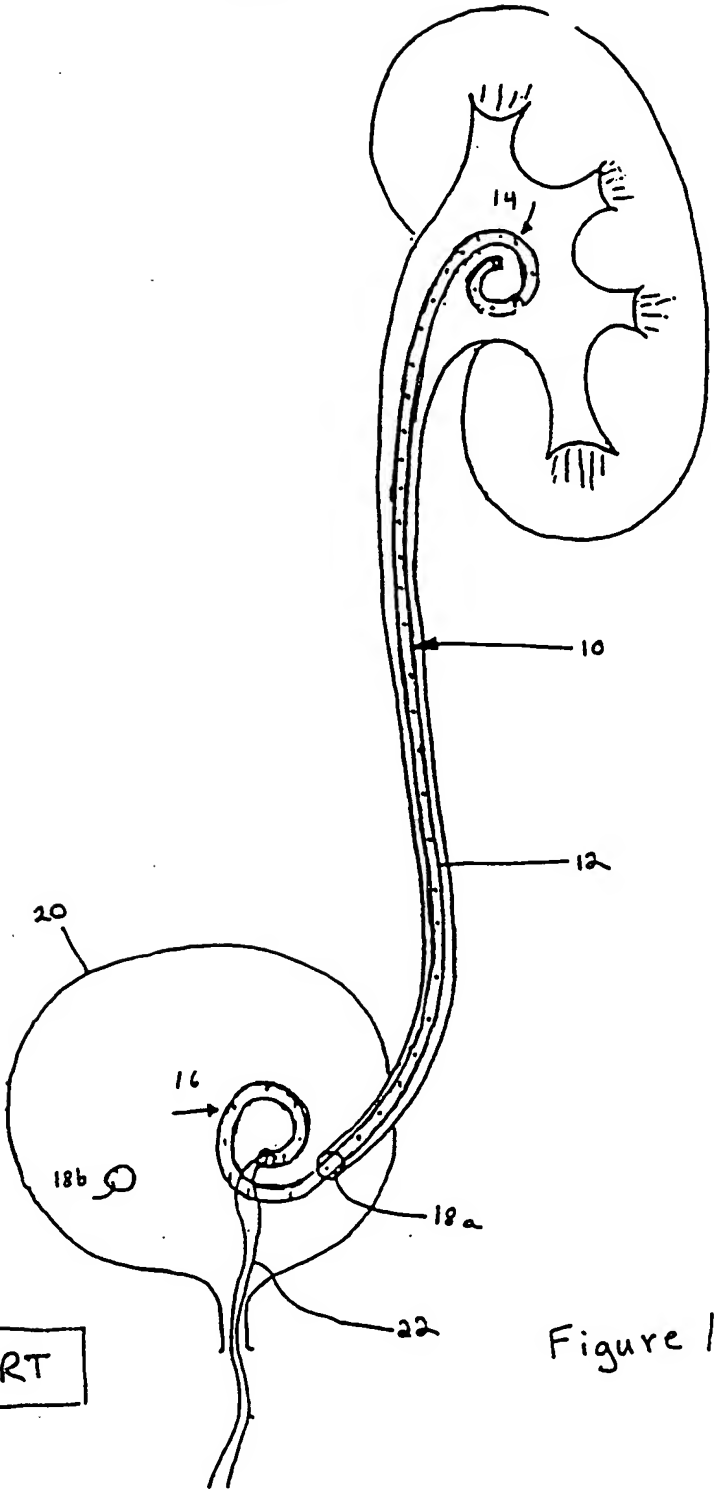


Figure 11

PRIOR ART



PRIOR ART

Figure 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17795

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00
US CL :604/8, 9

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/8, 9

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,671,795 A (MULCHIN) 09 June 1987, col. 2, lines 58-62.	1, 2, 5, 16, 36
A	US 4,913,683 A (GREGORY) 03 April 1990.	3, 4, 6-15, 17-35, 37- 40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 15 JANUARY 1997	Date of mailing of the international search report 13 FEB 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer KI YONG O Stacia Sinnik for Telephone No. (703) 308-2681

Form PCT/ISA/210 (second sheet)(July 1992)*

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TX 31651 epo nl
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01194/403W01

FREEMAN, John, W.
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

ETATS-UNIS D'AMERIQUE

Datum/Date
11/07/97

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n°.//Patent Nr./Patent No./Brevet n°.
	96940309.6- -PCT/US9617795

Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire
BOSTON SCIENTIFIC CORPORATION

NOTE: The following information concerns the steps which you are required to take for entry into the regional phase before the EPO. You are strongly advised to read it carefully. Failure to take the appropriate steps in due time could lead to the application being deemed withdrawn.

1. European patent application no. 96940309.6 has been allotted to the above-mentioned international patent application.

2. Applicants having neither a residence nor their principal place of business within the territory of one of the EPC Contracting States may initiate the regional (European) processing of the international application themselves, provided they do so before expiry of the 21st or 31st month as from the priority date (see Legal Advice of the EPO no. 18/92 published in OJ EPO 1992, 58).

   Note, however, that such applicants must be represented in the regional phase before the EPO as designated or elected Office by a professional representative whose name appears on the EPO list of representatives (Arts. 133(2) and 134(1) EPC).

   After expiry of the 21st or 31st month, any procedural steps which are taken by the representative of the applicant in the international phase, who is not, however, entitled to practise before the EPO, will have no effect and will, thus, result in loss of rights.

   The appointment of a professional representative entitled to practise before the EPO is possible/advisable at an early stage during the international phase (any time after the 14th month from the priority date) in view of representing applicants before the EPO as designated or elected Office.

* No Docketing Required *
Reviewed By Practice Systems
Initials: HE
Reviewed By Billing Secretary
Initials: JMN

--/4

EPO FORM 1201 (12.96)

04/07/97
000

Th refore, an app intment in due time is strongly recommended, if it is intended that this representative should already act for entry into the regional phase, otherwise all communications will be forwarded from the EPO directly to the applicant.

3. Applicants having their address within the territory of one of the EPC Contracting States are not obliged to appoint a professional representative entitled to practise before the EPO to represent them in the regional phase where the EPO is designated or elected Office.

   Note that due to the complexity of the proceedings, applicants are strongly advised to appoint such representative. Please keep in mind that, if a professional representative before the EPO has already acted for the applicant during the international phase, this representative is not automatically regarded as the representative for the regional phase.

4. Applicants and professional representatives are recommended to file EPO Form 1200 (available free of charge from the EPO) for entry into the regional phase. The use of Form 1200, however, is not mandatory.

5. FOR ENTRY INTO THE REGIONAL PHASE BEFORE THE EPO the following procedural steps must be taken. (Note that non-completion or ineffective completion of the required steps will result in loss of rights or other disadvantage.)

   5.1 Within 21 months from the date of filing or (where applicable) from the earliest priority date if the EPO acts as DESIGNATED OFFICE pursuant to Article 22(1) PCT:

   a) Filing of a translation of the international application in an EPO official language if the International Bureau did not publish the application in one of those languages (Art. 22(1) PCT and Rule 104b(1)(a) EPC).
   Note that if such translation is not filed in due time, the international application before the EPO is deemed withdrawn (Art. 24(1)(iii) PCT).

   b) Payment of the national fee [national basic fee, the designation fee for each State designated, (where applicable) the claims fees for the eleventh and each subsequent claim] and the search fee, where a supplementary European search report has to be drawn up (Rule 104b(1)(b), (c) EPC).

   Upon expiry of the 21-month time limit provided for in Rule 104b(1) EPC the EPO sends the applicant or his appointed professional representative the communication pursuant to Rule 85a(1) EPC (Form 1217) and (where applicable) Rule 69(1) EPC (Form 1205)

unless it has been notified of its designation as elected Office in due time.

5.2 Within 31 months from the date of filing or (where applicable) from the earliest priority date if the EPO acts as ELECTED OFFICE pursuant to Article 39(1)(a) PCT:

a) Filing of a translation as under 5.1 a).

b) Payment of the fees as under 5.1 b).

c) Filing of the written request for examination and payment of the examination fee (Rule 104b(1)(d) EPC).
Note that both acts must be performed in due time, otherwise the European patent application shall be deemed to be withdrawn (Art. 94(3) EPC).

d) Payment of the renewal fee for the third year, if due before the expiration of the 31-month term (Rule 104b(1)(e) EPC).

6. The amounts of the fees (equivalent in all currencies) are regularly published in the Official Journal of the EPO.

If the national basic fee, the designation fees or the search fee have not been paid in time, they may still be validly paid within a grace period of one month as from notification of an EPO communication (Rule 85a(1) EPC).

If the renewal fee is not paid in time, it may still be validly paid within six months from the due date (Art. 86(2) EPC).

In both cases, a surcharge is due.

7. The international search report under Article 18 PCT (or the declaration under Article 17(2)(a) PCT) has been published by the International Bureau. The date of publication can be ascertained from the copy of the published application documents sent by the International Bureau or from the international search report, if published separately. This publication takes the place of the mention of the publication of the European search report (Art. 157(1) EPC).

A request for examination, comprising a written request and payment of the examination fee, must be filed up to the end of six months after the above date.

However, in view of Article 22 or 39 PCT in conjunction with Rule 104b(1)(d) EPC, the period for filing the request for examination does not expire before 21 or 31 months, respectively, from the date of filing (where applicable, the earliest priority date).

A period of grace of one month from notification of an EPO communication is available in case either or both of the above acts have not been performed in time. Accordingly, a surcharge is due (Rule 85b EPC).

8. This information letter is addressed by the EPO to the agent, if any, having acted for the applicant during the international phase of the application.

   Any further notifications on procedural matters will be addressed to the applicant, respectively his European representative, if the appointment of the latter has been communicated to the EPO in due time. In case of non-resident applicants, notification shall be deemed to have been made when dispatch has taken place, even if the letter is returned to the sender owing to the impossibility of delivering it to the addressee (Rule 78(2) EPC).

9. For further details see the information for PCT applicants concerning time limits and procedural steps before the EPO as a designated and as an elected Office under the PCT (published as Supplement No. 1 to OJ EPO 12/1992, with changes published in OJ EPO 1994, 131).

RECEIVING SECTION

MZM
JJG

PATENT COOPERATION TREATY

RECEIVED

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JOHN W. FREEMAN
FISH & RICHARDSON P.C.
225 FRANKLIN STREET
BOSTON, MASSACHUSETTS 02110

FEB 18 1998

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing *(day/month/year)*	12 FEB 1998
Applicant's or agent's file reference: 01194/403W01	REPLY DUE within ONE months from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US96/17795	06 NOVEMBER 1996	07 NOVEMBER 1995

International Patent Classification (IPC) or both national classification and IPC
IPC(6): A61M 5/00; and US Cl.: 604/8, 9

Applicant
BOSTON SCIENTIFIC CORPORATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	[X]	Basis of the opinion
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Docketed by Billing Secretary
Due Date: 3/12/98
Deadline:
Initials: MB

Docketed by Practice Systems
PCT 1st written opinion 3/12/98
Initials: RNT
Record: 14393

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request the Authority to grant an extension., see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 07 MARCH 1998

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer KI O
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2681

Form PCT/IPEA/408 (cover sheet) (January 1994)★

WRITTEN OPINION

International application No.
PCT/US96/17795

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

☐ the international application as originally filed.

☒ the description, pages 1-18 , as originally filed.
pages NONE , filed with the demand.
pages NONE , filed with the letter of _____.

☒ the claims, Nos. 1-40 , as originally filed.
Nos. NONE , as amended under Article 19.
Nos. NONE , filed with the demand.
Nos. NONE , filed with the letter of _____.

☒ the drawings, sheets/~~fig~~ NONE , as originally filed.
sheets/~~fig~~ 1-10 , filed with the demand.
sheets/~~fig~~ NONE , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/~~fig~~ NONE

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:
NONE

WRITTEN OPINION

International application No.
PCT/US96/17795

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	3, 4, 6-14, 17-35, 38-40	YES
	Claims	1, 2, 5, 15, 16, 36, 37	NO
Inventive Step (IS)	Claims	3, 4, 6-14, 17-35, 38, 39	YES
	Claims	1, 2, 5, 15, 16, 36, 37, 40	NO
Industrial Applicability (IA)	Claims	1-40	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 2, 5, 15, 16, 36 and 37 lack novelty under PCT Article 33(2) as being anticipated by Mulchin (4,671,795). Mulchin discloses a ureteral stent having a thin flexible elongated member with an external urine transport surface sized and configured to transport urine along the surface within the ureter. It is sized and configured to extend along at least part of the ureter, across the ureter/bladder junction and into the bladder, as shown in Fig. 2. It contains an extractor, fluted tread filament as shown in Fig. 1. It is considered to have a continuous surface of a solid member extending from the kidney to the bladder.

Claims 3, 4, 6-14, 17-35, 38 and 39 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the following:

Claims 3, 4, 12-14, 17-35 and 38, the elongated member being at least one thin flexible tail extending from the lower region of the tubular segment at a point outside the bladder so as to receive urine from the second opening of the tubular segment, and to transport urine from the second region across the ureter/bladder junction and into the bladder. In regards to Claims 6 and 11, the multiple thread filaments.

Claims 7-10, the tail comprising at least one filament loop.

Claim 39, all the steps including introducing a ureteral stent having all the features including a central lumen connecting the first opening to the second opening, the elongated member being a thin flexible tail extending from the lower region of the tubular segment at a point outside the bladder, so as to receive urine from the second opening of the tubular segment, and to transport urine from the second region across the ureter/bladder junction and into the bladder.

Claim 40 lacks an inventive step under PCT Article 33(3) as being obvious over Mulchin (4,671,795). The methods are common and inherent for the use of the Mulchin catheter.

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

TIME LIMIT:

THE TIME LIMIT SET FOR RESPONSE TO A WRITTEN OPINION MAY NOT BE EXTENDED. 37 CFR 1.484(D). ANY RESPONSE RECEIVED AFTER THE EXPIRATION OF THE TIME LIMIT SET IN THE WRITTEN OPINION WILL NOT BE CONSIDERED IN PREPARING THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (CONTINUED):

———— NEW CITATIONS ————

NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

JOHN W. FREEMAN
FISH & RICHARDSON P.C.
225 FRANKLIN STREET
BOSTON MA 02110

RECEIVED
JUL 16 1997

PCT

NOTIFICATION OF RECEIPT
OF DEMAND

(PCT Rule 61.1(b), first sentence
and Administrative Instructions, Section 601)

Date of mailing *(day/month/year)*	15 JUL 1997
Applicant's or agent's file reference: 01194/403W01	IMPORTANT NOTIFICATION
International application No.: PCT/US96/17795	International filing date *(day/month/year)*: 06 NOV 96
Priority date *(day/month/year)*: 07 NOV 95	
Applicant: BOSTON SCIENTIFIC CORPORATION	

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

05 JUN 1997

2. This date of receipt is:

☒ the actual date of receipt of the demand.

☐ the date on which the proper corrections to the demand were timely received.

* No Docketing Required
Reviewed By Practice Systems
Initials: MO
Reviewed By Billing Secretary
Initials: JHB

3. ☐ This date is **AFTER** the expiration of 19 months from the priority date.

Attention: The election(s) made in the demand does (do) not have the effect of postponing the commencement of the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22).

For details, see Annex B to Form PCT/IB/301 sent by the International Bureau and Volume II of the PCT Applicant's Guide.

☐ This notification confirms the information given in person or by telephone on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/US Assistant Commissioner for Patents Box PCT Washington, D.C. 20231 Attn: IPEA/US Facsimile No.	Authorized officer Telephone No. 703-305-3664

Form PCT/IPEA/402 (July 1992)

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference: 01194/403W01

International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/US96/17795	06 November 1996 (06.11.96)	07 November 1995 (07.11.95)

Title of invention

URETERAL STENT WITH SMALL BLADDER TAIL(S)

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BOSTON SCIENTIFIC CORPORATION
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

Telephone No.:

Facsimile No.:

Teleprinter No.:

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
US	US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

CLAYMAN, Ralph V.
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
US	US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

DASSA, Alyssa J.
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
US	US

[X] Further applicants are indicated on a continuation sheet.

International application No.
PCT/US96/17795

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet is not to be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

FISHBEIN, Christopher
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
US	US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GODSHALL, Douglas E.
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
US	US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

WHITMORE, Willet F., III
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
US	US.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:

☐ Further applicants are indicated on another continuation sheet.

International application No.
PCT/US96/17795

Box No. III AGENT OR COMMON REPRESENTATIVE: OR ADDRESS FOR CORRESPONDENCE

The following person is [X] agent [ ] common representative

and [X] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[ ] is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

FREEMAN, John W.
Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
United States of America

Telephone No.: 617-542-5070

Facsimile No.: 617-542-8906

Teleprinter No.:

[ ] Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV STATEMENT CONCERNING AMENDMENTS

The applicant wishes the International Preliminary Examining Authority*

(i) [X] to start the international preliminary examination on the basis of the international application as originally filed.

(ii) [ ] to take into account the amendments under Article 34 of

- [ ] the description (amendments attached).
- [ ] the claims (amendments attached).
- [ ] the drawings (amendments attached).

(iii) [ ] to take into account any amendments of the claims under Article 19 filed with the International Bureau (a copy is attached).

(iv) [ ] to disregard any amendments of the claims made under Article 19 and to consider them as reversed.

(v) [ ] to postpone the start of the international preliminary examination until the expiration of 20 months from the priority date unless that Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Box No. V ELECTION OF STATES

[X] The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)* except .....
.....
.....
.....

(If the applicant does not wish to elect certain eligible States, the name(s) or country code(s) of those States must be indicated above.)

International application No.
PCT/US96/17795

Box No. VI CHECK LIST

The demand is accompanied by the following documents for the purposes of international preliminary examination:			For International Preliminary Examining Authority use only: received	not received
1. amendments under Article 34				
description	:	sheets	☐	☐
claims	:	sheets	☐	☐
drawings	: 10	sheets	☐	☐
2. letter accompanying amendments under Article 34	: 0	sheets	☐	☐
3. copy of amendments under Article 19	:	sheets	☐	☐
4. copy of statement under Article 19	:	sheets	☐	☐
5. other *(specify)*:	:	sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☒ fee calculation sheet
5. ☒ other *(specify)*: Transmittal Letter

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

John W. Freeman

John W. Freeman

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:
2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):
3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5. below, does not apply. ☐ The applicant has been informed accordingly.
4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

See Notes to the demand form

CHAPTER II

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

International application No. PCT/US96/17795	For International Preliminary Examining Authority use only
Applicant's or agent's file reference 01194/403W01	Date stamp of the IPEA

Applicant
BOSTON SCIENTIFIC CORPORATION; CLAYMAN, Ralph V.; DASSA, Alyssa J.; FISHBEIN, Christopher; GODSHALL, Douglas E.; and WHITMORE, Willet F., III

Calculation of prescribed fees

1. Preliminary examination fee	480.00 P	
2. Handling fee *(Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.)*	162.00 H	
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box	$642.00 TOTAL	

Mode of Payment

☐	authorization to charge deposit account with the IPEA (see below)	☐	cash
☒	cheque	☐	revenue stamps
☐	postal money order	☐	coupons
☐	bank draft	☐	other *(specify)*:

Deposit Account Authorization *(this mode of payment may not be available at all IPEAs)*

The IPEA/ US ☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☒ *(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)* is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

06/1050	6/4/97	John W. Freeman
Deposit Account Number	Date *(day month year)*	Signature John W. Freeman

PC[illegible]

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For Receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 01194/403WO1

Box No. I TITLE OF INVENTION

URETERAL STENT WITH SMALL BLADDER TAIL(S)

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BOSTON SCIENTIFIC CORPORATION
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(i.e. country)* of nationality: US

State *(i.e. country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

CLAYMAN, Ralph V.
c/o Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: US

State *(i.e. country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☐ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

FREEMAN, John W.
Fish & Richardson P.C.
225 Franklin Street
Boston, Massachsetts 02110-2804
United States of America

Telephone No. (617) 542-5070

Facsimile No. (617) 542-8906

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

DASSA, Alyssa J.
c/o Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: US

State *(i.e. country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

FISHBEIN, Christopher
c/o Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: US

State *(i.e. country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GODSHALL, Douglas E.
c/o Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: US

State *(i.e. country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

WHITMORE, Willett F. III
c/o Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537
United States of America

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: US

State *(i.e. country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked)*:

Regional Patent

- [X] AP **ARIPO Patent:** KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- [X] EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- [X] EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- [X] OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- [X] AL Albania
- [X] AM Armenia
- [X] AT Austria
- [X] AU Australia
- [X] AZ Azerbaijan
- [X] BB Barbados
- [X] BG Bulgaria
- [X] BR Brazil
- [X] BY Belarus
- [X] CA Canada
- [X] CH and LI Switzerland and Liechtenstein
- [X] CN China
- [X] CZ Czech Republic
- [X] DE Germany
- [X] DK Denmark
- [X] EE Estonia
- [X] ES Spain
- [X] FI Finland
- [X] GB United Kingdom
- [X] GE Georgia
- [X] HU Hungary
- [X] IL Israel
- [X] IS Iceland
- [X] JP Japan
- [X] KE Kenya
- [X] KG Kyrgyzstan
- [X] KP Democratic People's Republic of Korea
- [X] KR Republic of Korea
- [X] KZ Kazakstan
- [X] LK Sri Lanka
- [X] LR Liberia
- [X] LS Lesotho
- [X] LT Lithuania
- [X] LU Luxembourg
- [X] LV Latvia
- [X] MD Republic of Moldova
- [X] MG Madagascar
- [X] MK The former Yugoslav Republic of Macedonia
- [X] MN Mongolia
- [X] MW Malawi
- [X] MX Mexico
- [X] NO Norway
- [X] NZ New Zealand
- [X] PL Poland
- [X] PT Portugal
- [X] RO Romania
- [X] RU Russian Federation
- [X] SD Sudan
- [X] SE Sweden
- [X] SG Singapore
- [X] SI Slovenia
- [X] SK Slovakia
- [X] TJ Tajikistan
- [X] TM Turkmenistan
- [X] TR Turkey
- [X] TT Trinidad and Tobago
- [X] UA Ukraine
- [X] UG Uganda
- [X] US United States of America

.....continuation.....

- [X] UZ Uzbekistan
- [X] VN Viet Nam

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- [X] CU Cuba
- [ ] .....
- [ ] .....

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Supplemental Box *If the Supplemental Box is not used, this sheet need not be included in the request.*

Use this box in the following cases:

1. If, in any of the Boxes, the space is insufficient to furnish all the information:	*in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient;*
in particular:	
(i) if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available:	*in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III;*
(ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked:	*in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;*
(iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America:	*in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*
(iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents:	*in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*
(v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "Continuation" or "Continuation-in-part":	*in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;*
(vi) if there are more than three earlier applications whose priority is claimed:	*in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.*
2. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelty:	*in such case, write "Statement Concerning Non-Prejudicial Disclosures or Exceptions to Lack of Novelty" and furnish that statement below.*

US: 60/006,259 07 November 1995 (07.11.95)

US: 60/025,284 19 September 1996 (19.09.96)

Box No. VI PRIORITY CLAIM Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country *(in which, or for which, the application was filed)*	Filing Date *(day/month/year)*	Application No.	Office of filing *(only for regional or international application)*
item (1) US	(07.11.95) 07 November 1995	60/006,259	
item (2) US	(19.09.96) 19 September 1996	60/025,284	
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): (1) (2)

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA / US

Earlier search *Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request.*

Country (or regional Office): Date *(day/month/year)*: Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request	5	sheets
2. description	18	sheets
3. claims	6	sheets
4. abstract	1	sheets
5. drawings	12	sheets
Total	42	sheets

This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☐ priority document(s) *identified in Box No. VI as item(s):*
5. ☒ fee calculation sheet
6. ☐ separate indications concerning deposited microorganisms
7. ☐ nucleotide and/or amino acid sequence listing (diskette)
8. ☒ other *(specify)*: Transmittal Letter

Figure No. 8 of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Boston Scientific Corporation
Ralph V. Clayman
Alyssa J. Dassa
Christopher Fishbein
Douglas E. Godshall
Willett F. Whitmore III

John W. Freeman
Attorney for Applicant/Applicant-Inventors

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority specified by the applicant: ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

International application No.

Date stamp of the receiving Office

Applicant's or agent's file reference: 01194/403W01

Applicant: BOSTON SCIENTIFIC CORPORATION

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE . . . . . 230 [T]

2. SEARCH FEE . . . . . 430 [S]

International search to be carried out by ISA/US

(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains 42 sheets.

first 30 sheets . . . . . 677 [b_1]

12 (remaining sheets) x 13 (additional amount) = 156 [b_2]

Add amounts entered at b_1 and b_2 and enter total at B . . . . 833 [B]

Designation Fees

The international application contains all designations.

(number of designation fees payable *(maximum 11)*) x (amount of designation fee) = 1804 [D]

Add amounts entered at B and D and enter total at I . . . . . 2637 [I]

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT . . . . . 15 [P]

5. TOTAL FEES PAYABLE

Add amounts entered at T, S, I and P, and enter total in the TOTAL box . . 3312 TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

- ☐ authorization to charge deposit account (see below)
- ☒ cheque
- ☐ postal money order
- ☐ bank draft
- ☐ cash
- ☐ revenue stamps
- ☐ coupons
- ☐ other *(specify)*:

DEPOSIT ACCOUNT AUTHORIZATION *(this mode of payment may not be available at all receiving Offices)*

The RO/ US

- ☐ is hereby authorized to charge the total fees indicated above to my deposit account.
- ☒ is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.
- ☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

Deposit Account Number	Date *(day/month/year)*	Signature
06-1050	11/6/96	John W. Freeman John W. Freeman